

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and)	
BOSTON SCIENTIFIC SCIMED, INC.,)	
)	
Plaintiffs,)	C.A. No. 07-333-SLR
)	C.A. No. 07-348-SLR
v.)	C.A. No. 07-409-SLR
)	
JOHNSON & JOHNSON, INC. and)	
CORDIS CORPORATION,)	
)	
Defendants.)	
<hr/>		
BOSTON SCIENTIFIC CORPORATION and)	
BOSTON SCIENTIFIC SCIMED, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 07-765-SLR
)	
JOHNSON & JOHNSON, INC.,)	
CORDIS CORPORATION, and WYETH,)	
)	
Defendants.)	

**CORDIS'S OPPOSITION TO BSC'S MOTION
FOR LEAVE TO FILE AN AMENDED COMPLAINT**

Of Counsel:

David T. Pritikin
William H. Baumgartner, Jr.
Russell E. Cass
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

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ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Lauren E. Maguire (I.D. #4261)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

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Introduction

The Court set a deadline of July 25, 2008 for the filing of amended pleadings in this case. (Case No. 07-333, D.I. 48) Plaintiffs Boston Scientific Corporation and Boston Scientific SciMed, Inc. (collectively “BSC”) never asked for this date to be extended. Their present motion to amend the pleadings (filed December 23, 2008) is therefore five months late. The motion should be denied because it is untimely and because the belated addition of new inequitable conduct issues would seriously prejudice defendants Johnson & Johnson, Inc., Cordis Corporation, and Wyeth (collectively “Cordis”).

BSC misstates the law, and in so doing it fails to address the correct standard that applies to its motion. Motions for leave to amend pleadings made after the deadline set in a court’s scheduling order are governed by Federal Rule of Civil Procedure 16(b). Contrary to what BSC argues, the Third Circuit treats Rule 16(b), which requires good cause to alter a court’s scheduling order, as a distinct standard from Federal Rule of Civil Procedure 15. *See Eastern Minerals & Chemicals Co. v. Mahan*, 225 F.3d 330, 340 (3d. Cir. 2000); *Venetec Inter. Inc. v. Nexus Medical, LLC*, 541 F. Supp. 2d. 612, 618 (D. Del. 2008). To satisfy the good cause requirement, a party must have worked “diligently” to comply with the schedule. *Venetec Inter. Inc.* 541 F. Supp. 2d at 618.

BSC makes a number of excuses for having missed the deadline for amending pleadings by five months. None satisfies the diligence requirement of Rule 16(b). BSC points to the fact that Defendants located and produced documents after the July 25, 2008 deadline, but fails to explain how these documents (the vast majority of which were produced many months ago) were required in order to file the amendments at issue. To the contrary, most of BSC’s

allegations rely on publicly available patents and prosecution histories that were in BSC's possession long before the July 25, 2008 deadline. BSC also spills considerable ink about cancelled and delayed depositions (which were cancelled by Abbott), but again fails to explain how any such deposition testimony was necessary to file the amended contentions at issue here. Indeed, BSC apparently decided to amend its complaint *prior to taking any depositions* in this case. These arguments appear to be little more than a smokescreen to cover BSC's lack of diligence in preparing its amended complaint. Because BSC did not diligently attempt to comply with the Court's scheduling order, it does not have good cause to amend its complaint now.

Cordis has been prejudiced by BSC's failure to meet the July 25, 2008 deadline for amending the pleadings. If new inequitable conduct allegations are added five months after the deadline, Cordis will be prejudiced by having missed the opportunity to question third-party witnesses at past depositions on matters relating to the new allegations. To the extent that these third party witnesses are recalled for further deposition testimony, they will be inconvenienced and subjected to unnecessary burden.

Even analyzed under Rule 15, BSC's motion fails. Courts do not grant leave to amend under Rule 15 when the moving party unduly delayed in filing the motion or when the non-moving party would be unduly prejudiced. Both of these circumstances are present in this case. BSC offers no reasonable explanation for its extended delay, and this unexplained delay qualifies as undue delay. Moreover, as indicated above, Cordis will be prejudiced by BSC's delay. Accordingly, BSC's motion fails to meet the standards of Rule 15 and should be denied.

Background

BSC did not include any allegations of inequitable conduct in its initial pleadings. The Scheduling Order in this case, as amended on July 21, 2008, provides that motions to amend

the pleadings were due to be filed on July 25, 2008. *See* Case No. 07-333, D.I. 48. The July 25, 2008 date came and went without BSC moving to extend the pleadings. Nor did BSC approach Cordis about amending the pleadings or extending the deadline before July 25, 2008.

To the contrary, BSC did not even raise the possibility of amending the pleadings to add inequitable conduct until over two months later, on October 7, 2008. (Spanbauer Decl. Exhibit A). On October 15, Cordis's counsel requested a copy of the proposed amended pleadings, (Spanbauer Decl. Exhibit B), and BSC replied that "[w]e are finalizing a draft amended complaint and will send it to you when ready" (Spanbauer Decl. Exhibit C). BSC, however, failed to pursue the matter diligently. The promised draft amended pleadings did not arrive until the day before Thanksgiving (November 26)—a month and a half later. (Spanbauer Decl. Exhibit D) In the interim, BSC had proposed and agreed to modifications to the scheduling order to extend other dates, such as the close of fact discovery, but made no request to extend the date for amending pleadings. (See Spanbauer Decl. Exhibits E, F; Case No. 07-333, D.I. 102)¹ BSC's Motion to Amend was ultimately filed at the close of business on December 23.

Argument

I. BECAUSE BSC FILED ITS MOTION TO AMEND AFTER THE COURT'S DEADLINE, IT MUST MEET THE "GOOD CAUSE" REQUIREMENT OF RULE 16

Once Cordis served its answer, BSC was obligated to obtain the Court's leave in order to amend its complaint. *See* Fed. R. Civ. P. 15(a)(2). But BSC seeks to amend its pleading

¹ This was not the first time BSC approved modifications to a scheduling order without even mentioning modifying the deadline for amending pleadings. Amended scheduling orders were filed on April 10, 2008 (*see* Case No. 07-333, D.I. 41) and July 17, 2008 (*see* Case No. 07-333, D.I. 48); the deadline for amending pleadings has not moved since July 21, 2008. *See* Case No. 07-333, D.I. 48.

not only after Cordis's answer, but also after the July 25 deadline for amending pleadings set by the Court's scheduling order. Because granting BSC's motion would "in effect, operate to change the scheduling order," Fed. R. Civ. P. 16(b)(4) controls the outcome. *Venetec Inter. Inc. v. Nexus Medical, LLC*, 541 F. Supp. 2d. 612, 618 (D. Del. 2008). BSC does not articulate the correct standard under Rule 16 as interpreted by the Third Circuit. Even if BSC had correctly articulated the courts' interpretation of Rule 16, it could not meet that standard.

Fed. R. Civ. P. 16(b)(4) states that "[a] schedule may be modified only for good cause and with the judge's consent." BSC, citing a single district court case, asserts that "good cause" is present whenever a party can show that "justice so requires" the amendment; in other words, when the moving party meets the standard of Fed. R. Civ. P. 15(a).² See BSC Br. at 6. But this misstates the law. The Third Circuit has held that the two rules create distinct standards. See *Eastern Minerals & Chemicals Co. v. Mahan*, 225 F.3d 330, 340 (3d. Cir. 2000) (upholding district court decision to deny leave to amend without examining moving party's Rule 15(a) argument); see also *Dimensional Communications, Inc. v. OZ Optics, Ltd.*, 148 Fed. Appx. 82, 85 (3d. Cir. 2005) ("failure to satisfy Rule 16(b)'s 'good cause' requirement was sufficient to deny a motion to amend filed six months after the deadline"); *Venetec Inter. Inc.*, 541 F. Supp. 2d. at 618 ("Unlike Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant and not on prejudice to the non-moving party."). And the Ninth Circuit explained the reason for applying Rule 16(b)'s more demanding standard in the present situation:

Disregard of the order would undermine the court's ability to control its docket, disrupt the agreed-upon course of the litigation, and reward the indolent and the cavalier. *Rule 16 was drafted to*

² The *Enzo* case that BSC relies on is cited by one unreported, one paragraph opinion: *Talecris Biotherapeutics, Inc. v. Baxter International, Inc.*, No. 05-349, 2007 WL 1670387 (D. Del. June 7, 2007), which fails to cite the controlling Third Circuit decisions and the relevant committee note to Rule 16.

prevent this situation and its standards may not be short-circuited by an appeal to those of Rule 15.

Johnson v. Mammoth Recreations, Inc., 975 F.2d 604, 610 (9th Cir. 1992) (emphasis added).

The two standards thus do not overlap, and BSC's motion must be evaluated under the distinct good cause standard.

II. BSC FAILS TO MEET THE DILIGENCE STANDARD UNDER RULE 16

Good cause under Rule 16 is present if the scheduling order cannot be met “despite the diligence of the party seeking the extension.” *Chancellor v. Pottsgrove School Dist.*, 501 F. Supp. 2d 695, 701 (E.D. Pa. 2007) (collecting authorities); *see also* Fed. R. Civ. P. 16 advisory cmte. note (1983) (requiring diligent effort to meet the deadline). This Court has characterized diligence as the “earnest or conscientious activity, if any, by [the moving party] to determine the appropriateness of [the claim] *before* [the deadline].” *Venetec International, Inc.*, 541 F. Supp. 2d at 622 (emphasis in original). BSC does not—and cannot—demonstrate a diligent effort to meet the deadline for amended pleadings.

A. BSC Makes No Showing of Diligence.

BSC's brief makes no showing of diligence. Indeed, the omissions in BSC's factual recitation permit the inference that BSC was not diligent. Tellingly, BSC's brief says nothing about when BSC first learned of the relevant facts. Nor does BSC's brief point to a document or deposition that alerted it to the possibility of inequitable conduct claims.

BSC has thus failed to meet its burden of demonstrating diligence, and this failure of proof is fatal. In the *Venetec* case, for example, the Court did not find good cause, because the moving party failed to explain the steps it took to investigate the new claims prior to the deadline in the scheduling order. *Id.* Similarly, in *Eastern Minerals*, the Third Circuit affirmed a district court ruling that found “good cause had not been shown under Rule 16(b)” because the movant

“had not specified what led it to decide that [the new claims] could be pled or why information from independent sources could not have been obtained earlier.” 225 F.3d at 340. BSC makes no effort to identify what led it to decide it could file inequitable conduct claims. Its entire explanation accounts for just two sentences of its brief:

While the deadline for amending pleadings was July 25, 2008, the majority of discovery, including a substantial percentage of Cordis’s document production, and all of the depositions occurred after this date. It was simply not possible for BSC to amend its complaint prior to that date.

BSC Br. at 8. Lacking from this “explanation” is any sort of description of the efforts BSC undertook to investigate or develop its claims. Without such an explanation, BSC cannot demonstrate a diligent effort to meet the deadline set in the Court’s scheduling order.

B. BSC’s Attempts to Blame Cordis’s Document Production Are Unavailing

While the issue here is whether BSC was diligent in pursuing a potential inequitable conduct claim, BSC tries to shift the focus to Cordis. BSC says that it should not be held to the July 25 deadline for amending the pleadings because Cordis produced documents after that date.

BSC leaves out some important facts. To start with, Cordis produced massive quantities of documents before July 25: approximately 1.7 million pages. (Spanbauer Decl. Ex. H pp. 1-7) This contrasts with the less than roughly 150,000 pages that BSC had produced as of July 25. (Spanbauer Decl. Ex. G) Although Cordis did locate and produce additional documents after July 25, the vast majority of those additional documents were produced by mid-September. (Spanbauer Decl. Ex. H pp. 8-12) Only a very small relative number were produced following that time. (Spanbauer Decl. Ex. H p. 15, Spanbauer Decl. ¶13) In addition, BSC misstates the number of documents produced by Cordis after July 25 – nearly doubling the actual number. (Spanbauer Decl. Ex. H, pp. 8-14, Spanbauer Decl. ¶13)

More significantly, BSC fails to explain how any of these documents that it received after July 25 were pertinent to the inequitable conduct allegations that BSC now seeks to inject into the case. In fact, as a cursory review of BSC's proposed amended pleading reveals, its inequitable conduct allegations are mainly based on publicly available documents, such as the specifications of the patents-in-suit, the prosecution histories of the patents-in-suit, and prior art patents and publications. *See* Civil Action No. 07-333, D.I. 125, Exhibits A-C, ¶¶ 34, 38, 42, 46, 50, 54, 62, 66, 68, 69, 72-74, 77-79 and Exhibit D ¶¶ 36-37, 39-40, 43-45, 53-55 (citing information gleaned from publicly available documents; almost all of the remaining allegations are based on "information and belief"), BSC had (or should have had) all of these documents long before the July 25 deadline for amending the pleadings.

C. BSC's Argument That Postponement of Depositions Justifies Its Delay Lacks Merit

BSC further asserts that it could not file its amended complaint without first taking depositions. But deposition testimony cannot possibly have played any role in BSC's development of its amended complaint. The first deposition in this case took place on October 14. *See* Civil Action No. 07-333, D.I. 125 ¶ 12. BSC, however, indicated that it would amend its complaint on October 7—before the first deposition even took place. (Spanbauer Decl. Ex. A) Logically, because BSC had decided to amend its claims prior to even taking any depositions, the date of the depositions could not have played a role in its decision.

D. Cordis Would Be Prejudiced By BSC's Belated Amendment of Its Pleadings

BSC argues that because Cordis already has to defend against Abbott's inequitable conduct allegations, adding its own will not prejudice Cordis. BSC's proposed pleadings, however, add seven additional allegations of inequitable conduct in Civil Action Nos.

07-333, 07-348, and 07-409 and three additional allegations in 07-765.³ *See* Civil Action No. 07-333, D.I. 125, Exhibits A-C ¶ 32; Exhibit D ¶¶ 54-56. For example, BSC makes allegations relating to the state of the art of polymer coatings at the time of the filing of the patents-in-suit. At this late stage of the case, investigating and responding to these allegations would consume additional resources and complicate an already busy schedule.

There is further prejudice to Cordis because third party depositions have been taken where Cordis had no reason to question the witnesses about the issues that are now raised in the proposed amended pleadings. For example, the depositions of third party witnesses Brian Firth (a physician) and Mark Roller (a Ph.D. chemist) were taken on November 13-14 and 20-21, respectively, before BSC provided its proposed amended pleadings to Cordis. Cordis questioned both witnesses extensively. However, Cordis did not elicit testimony from the witnesses concerning BSC's new allegations and would need to redepose them to do so.

III. BSC CANNOT EVEN MEET RULE 15'S MORE LENIENT STANDARD

Even ignoring Rule 16, BSC's motion for leave to amend should not be granted. The motion fails even under the more lenient standard of Rule 15. Rule 15 states that a court should grant leave to amend whenever "justice so requires." *See* Fed. R. Civ. Pro. 15(a)(2). Two of the circumstances for which courts deny leave to amend—undue delay and undue prejudice—are present here. *See Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989).

A. BSC's Motion Was Unduly Delayed

Several courts have held that when a party's delay in seeking leave to amend is unexplained, the delay was "undue." *See, e.g., Quaker State Oil Refining Corp. v. Garrity Oil*

³ To the extent Abbott's claims are relevant to the present issue, they show that BSC should not be granted leave to amend: Abbott filed its amend pleadings months ago; BSC knew this and still delayed significantly in preparing its own amended pleadings.

Co., 884 F.2d 1510, 1518 (1st Cir. 1989) (“Most important, defendant never proffered a satisfactory explanation for its delay.”); *Deasy v. Hill*, 833 F.2d 38, 41 (4th Cir. 1987) (holding delay was undue when the movant “failed to offer to the trial court . . . *any* reason for his delay”) (emphasis in original). In addition, the Third Circuit has held that when the facts of the amendment were known to the moving party long before amendment is sought, the burden shifts to the moving party to give a valid reason for the delay. *See Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d. Cir. 1993).

BSC’s only justification for its delay is a general complaint about the pace of discovery and depositions. Obviously, however, deposition testimony played no part in BSC’s decision to seek leave to amend, because the first deposition in this case took place *after* BSC sought Cordis’s consent for the amendment.

BSC’s general complaints about the pace of document production does not explain its delay in filings its motion. As discussed previously, most of BSC’s allegations come from publicly available documents, such as the specifications of the patents-in-suit, the prosecution histories of the patents-in-suit, and prior art patents and publications. Even if the allegations were supported by evidence collected during discovery, BSC’s brief does not point to a single document that lead to the allegations of its amended complaint. In other words, BSC demonstrated that discovery moved slower than the parties would have liked; it did not demonstrate a causal relationship between this and its delay. In effect, BSC has offered no explanation at all. Because the delay is unexplained, it is “undue,” and the Court should not grant BSC leave to amend.

B. Granting BSC’s Motion Would Cause Undue Prejudice to Cordis

A party is unduly prejudiced by an amended pleading if the amendment would “(i) require the opponent to expend significant additional resources to conduct discovery and

prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction.” *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004). As explained above, because defending against BSC’s amended pleadings would delay the resolution of this dispute and cause Cordis to expend significant additional resources, Cordis would be unduly prejudiced if BSC receives leave to amend.

The Federal Circuit has recognized that “[i]ssues of inequitable conduct are most difficult . . . for trial courts.” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995). Charges of inequitable conduct have “come to be attached to every patent prosecution, diverting the court from genuine issues and simply spawning satellite litigation.” *Multiform Desiccants, Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998). If BSC can add inequitable conduct charges, Cordis may be forced to redepose witnesses, go back through many pages of its own documents, and engage in motion practice that will prolong already complicated litigation.

Conclusion

BSC did not work diligently to investigate or develop its amended complaint—either before or after the deadline for amended pleadings in the Court’s scheduling order. Consequently, BSC does not have good cause to alter the scheduling order. BSC’s failure to explain its delay in bringing this motion also causes it to fail Rule 15’s standard for motions to amend. Because BSC flunks both of the applicable standards, the Court should deny its motion for leave to file an amended complaint.

ASHBY & GEDDES

/s/ *Lauren E. Maguire*

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Lauren E. Maguire (I.D. #4261)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
lmaguire@ashby-geddes.com

Attorneys for Defendants

Of Counsel:

David T. Pritikin
William H. Baumgartner, Jr.
Russell E. Cass
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

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